



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 168

[EPA-HQ-OPP-2009-0607; FRL-9913-19]

RIN 2070-AJ53

Labeling of Pesticide Products and Devices for Export; Clarification of Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the regulations that pertain to the labeling of pesticide products and devices that are intended solely for export. These amendments clarify that pesticide products and devices that are intended solely for export must meet the Agency's labeling requirements by attaching a label to the immediate product container or by providing collateral labeling that is either attached to the immediate product being exported or that accompanies the shipping container of the product being exported at all times when it is shipped or held for shipment in the United States.

Collateral labeling will ensure the availability of the required labeling information, while allowing pesticide products and devices that are intended solely for export to be labeled for use in and consistent with the applicable requirements of the importing country.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2009-0607, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; email address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Affect Me?

You may be potentially affected by this action if you export a pesticide product, a pesticide device, or an active ingredient used in producing a pesticide. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include, but are not limited to: Pesticide

and other agricultural chemical manufacturing (NAICS code 325320), e.g., Pesticides manufacturing, Insecticides manufacturing, Herbicides manufacturing, Fungicides manufacturing, etc.

B. What is the Agency's Authority for Taking this Action?

This action is issued under the authority of section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136w(a), to carry out the provisions of FIFRA section 17(a), 7 U.S.C. 136o(a).

C. What Action is the Agency Taking?

EPA is proposing to amend the regulations that pertain to the labeling of pesticide products and devices that are intended solely for export. These amendments clarify that pesticide products and devices that are intended solely for export must meet the Agency's labeling requirements by attaching a label to the immediate product container or by providing collateral labeling that is either attached to the immediate product being exported or that accompanies the shipping container of the product being exported at all times when it is shipped or held for shipment in the United States. Collateral labeling will ensure the availability of the required labeling information, while allowing pesticide products and devices that are intended solely for export to be labeled for use in and consistent with the applicable requirements of the importing country.

D. What are the Impacts of this Action?

There are no costs associated with this action, and the benefits provided are related to avoiding potential costs. Without these labeling provisions, registrants would be required to place export-related labeling on the immediate package of each individual pesticide product in a shipping container that is intended solely for export. According to

stakeholders, the inability to use the labeling method allowed under the previous regulations could significantly increase their costs and create trade barriers.

II. Background

A. The April 30, 2014 Direct Final Rule

Industry stakeholders subsequently brought to the Agency's attention their concern that removing the term "supplemental labeling" resulted in the removal of a provision stating that such supplemental labeling can be attached to a shipping container holding export pesticides or devices rather than to each individual product container in a shipment. They stated that the inability of registrants to use "supplemental labeling" in that manner could create trade barriers and increase costs. The purpose of the direct final rule EPA published in the **Federal Register** of April 30, 2014 (79 FR 24347) (FRL-9909-82) was to address those concerns as expeditiously as possible.

As indicated in the direct final rule, EPA now believes that the term "supplemental labeling" is not the appropriate term to describe the material or documentation used to meet the requirements of the export labeling rules. To more accurately describe the materials other than "labels" that are acceptable for meeting these requirements, EPA believes that a better term is "collateral labeling." EPA has already described collateral labeling in the Label Review Manual (LRM), p. 3-2 (see <http://www.epa.gov/oppfead1/labeling/lrm/chap-03.pdf>), as follows:

Bulletins, leaflets, circulars, brochures, data sheets, flyers or other written, printed or graphic matter which are referred to on the label or which are to accompany the product are known in Agency practice as "collateral labeling." Such labeling is subject to applicable requirements of FIFRA and the Agency's regulations.

Accordingly, the direct final rule used the term "collateral labeling" in restoring the

ability of exporters to comply with export labeling requirements through materials that are not attached to each individual export product's immediate container. The direct final rule provided amendments for revising existing 40 CFR 168.66 to remove the reference to 40 CFR 156.10(a)(4), and to restore the inadvertently eliminated provisions that allowed exporters to use such collateral labeling attached to, or accompanying, the product shipping container of the export pesticide at all times when shipped or held for shipment in the United States. The direct final rule also restructures 40 CFR part 168, subpart D, by moving the text in § 168.68 and some of the text in § 168.66 to new § 168.65.

B. Summary of the April 6, 2011 Proposed Rule

In the **Federal Register** of April 6, 2011 (76 FR 18995) (FRL-8862-2), EPA issued a proposed rule to clarify, restructure, and add specificity to labeling regulations for the export of unregistered pesticide products and devices. Additionally, that proposed rule explicitly requires labeling to accompany the unregistered export pesticide product or device at all times, even when such products are being shipped between registered establishments operated by the same producer.

C. Public Comments on the April 6, 2011 Proposed Rule

Six sets of comments were submitted. Two of the commenters pointed out several inconsistencies in the use of the terms "label," "labeling," and "supplemental labeling" in the proposed rule. One of those commenters also urged "that all labeling requirements should be in compliance with existing regulations under 40 CFR 156." The comments are available in the docket under docket ID number EPA-HQ-OPP-2009-0607.

EPA analyzed the comments and prepared a response to comments document,

which is available in the docket under document ID number EPA-HQ-OPP-2009-0607-0016. As part of analyzing the comment on inconsistencies in the use of the terms “label,” “labeling,” and “supplemental labeling,” EPA referred to FIFRA’s definitions of “label” and “labeling.” Section 2(p)(1) of FIFRA defines label as “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.” Under FIFRA section 2(p)(2), labeling is a more inclusive term which includes labels as well as “all other written, printed, or graphic matter” that accompanies the product at any time, or to which reference is made on a label or in literature accompanying the pesticide or device. Because the two terms are not interchangeable, EPA agreed that inconsistent use could create confusion. Thus, as EPA began to write the regulatory text for the final rule, the Agency carefully evaluated the regulatory text for possibly confusing uses of the terms “label” and “labeling.”

During that evaluation, and bearing in mind the comment that “all labeling requirements should be in compliance with existing regulations under 40 CFR 156,” EPA analyzed proposed § 168.66(b). Proposed § 168.66(b) specified that “the required label information may be fully met by” and then provided several examples of ways to provide the required label information. One of the examples referred to “supplemental labeling.” At that time, EPA determined to provide a reference to the existing label regulations in 40 CFR part 156, instead of providing examples of ways to meet the required label information. Specifically, EPA referred to 40 CFR 156.10(a)(4), believing that provision would provide appropriate and accurate information.

D. The January 18, 2013 Final Rule

The final rule entitled “Labeling of Pesticide Products and Devices for Export;

Clarification of Requirements’’ published in the **Federal Register** of January 18, 2013 (78 FR 4073) (FRL-9360-8). This final rule was effective on March 19, 2013, with a compliance date of January 21, 2014.

III. Withdrawal of the April 30, 2014 Direct Final Rule

In the preamble to the direct final rule, EPA explained the Agency’s reasons for these amendments, and that we would withdraw that direct final rule if written adverse comment were received within 30 days of the publication of that direct final rule. Since EPA received written adverse comments, elsewhere in this issue of the **Federal Register**, EPA has withdrawn the direct final rule, and the direct final rule will not take effect.

In accordance with the procedures described in the April 30, 2014 direct final rule, EPA is publishing this proposed rule.

IV. Issues Raised by the Adverse Comments

EPA received two written adverse comments in response to the direct final rule. Both commenters indicated their disagreement with EPA’s approach on the use of collateral labeling. Their comments indicated their belief that individual pesticide products should be properly labeled, even if intended solely for export. One commenter indicated that this would only “benefit the large pesticide producers, allowing them to cut the cost of production by not properly labeling everything.” The other commenter indicated that labeling “is critical to safe and rational use of pesticides.”

EPA believes that both commenters misinterpreted the intent of the direct final rule and interpreted the direct final rule as removing or eliminating requirements. The amendments specified in the direct final rule do not remove or eliminate label requirements for individual pesticide products or devices that are intended solely for

export. The amendments would have simply clarified that the label requirements for products intended for export can be met with labeling on the individual products with the addition of collateral labeling attached to either the product or the product shipment container.

Typically, products that are manufactured in the United States for export bear a label which meets the requirements of the importing country. Since that label may not meet all the FIFRA labeling requirements contained in 40 CFR part 168, the regulations previously allowed for these products to meet those requirements by labeling attached to the shipping container. As an example, a shrink-wrapped pallet of cartons would have only one FIFRA export label attached to the shrink-wrap. A pallet of unwrapped cartons, on the other hand, would have FIFRA export labels attached to each carton. In both cases, the individual products in those cartons are individually labeled for use in the importing country and in compliance with the applicable labeling requirements of that importing country. EPA believes that collateral labeling is appropriate for shipping containers holding pesticide products and devices that are intended solely for export because it ensures the availability of the information provided by the FIFRA export label requirements while those products are in transit in the United States.

The amendments specified in the direct final rule were not to establish a new or substantively different requirement from that which existed until 2013, when a final rule inadvertently deleted the applicable provisions. After considering these adverse comments, EPA has determined no changes are needed, and is proposing the same regulatory text as that in the April 30, 2014 direct final rule.

V. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA previously submitted the draft proposed rule to the Secretary of Agriculture (USDA), the FIFRA Scientific Advisory Panel (SAP), and the appropriate Congressional Committees. On February 10, 2014, the FIFRA SAP waived its review of this proposed rule because the changes “are administrative in nature and do not contain scientific issues that require the SAP’s consideration.” On March 12, 2014, USDA waived review of this proposed rule, because this action merely “corrects the regulatory text.”

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed rule is not a “significant regulatory action” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and was not, therefore, submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, as applicable.

The information collection requirements associated with reporting under 40 CFR part 168 have already been approved by OMB pursuant to PRA under OMB control

number 2070-0027 (EPA ICR No. 0161). This proposed rule is not expected to involve an increase in information collection activities. There are no additional burdens imposed by this proposed rule that requires additional review or approval by OMB.

C. Regulatory Flexibility Act (RFA)

I certify that this action, if finalized as proposed, will not have a significant economic impact on a substantial number of small entities under RFA, 5 U.S.C. 601 *et seq.* In making this determination, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of an initial regulatory flexibility analysis is to identify and address regulatory alternatives “which minimize any significant economic impact of the rule on small entities” 5 U.S.C. 603. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden effect on the small entities subject to the rule. As indicated previously, EPA is restoring a provision that was inadvertently removed from the regulation. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any State, local, or Tribal governments, because no State, local, or Tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices. As indicated previously, EPA is restoring a provision that was inadvertently removed from the regulation.

E. Executive Order 13132: Federalism

This action will not have substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have tribal implications because it is expected to only affect producers, transporters, formulators, packagers, and exporters of unregistered pesticide products and devices. Since no Indian Tribal government is known to produce, transport, formulate, package, or export unregistered pesticide products or devices, this action has no tribal implications. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this proposed rule.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. As such, this action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 168

Environmental protection, Administrative practice and procedure, Advertising, Exports, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 3, 2014.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 168--[AMENDED]

1. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136-136y.

2. Revise the heading for subpart D to part 168 to read as follows:

Subpart D--Procedures for Exporting Pesticides

3. Add § 168.65 to subpart D to read as follows:

§ 168.65 Applicability.

(a) This subpart describes the labeling requirements applicable to pesticide products and devices that are intended solely for export from the United States under the provisions of FIFRA section 17(a).

(b) This subpart applies to all export pesticide products and export pesticide devices that are exported for any purpose, including research.

(c) Export pesticide products and export pesticide devices are also subject to requirements for pesticide production reporting, recordkeeping and inspection, and purchaser acknowledgement provisions that can be found in the following parts:

(1) Pesticide production reporting requirements under FIFRA section 7 are located in part 167 of this chapter (as referenced in § 168.85(b)).

(2) Recordkeeping and inspection requirements under FIFRA section 8 are located in part 169 of this chapter (as referenced in § 168.85(a)).

(3) Purchaser acknowledgement statement provisions under FIFRA section 17(a) are located in § 168.75.

4. Revise § 168.66 to read as follows:

§ 168.66 Labeling of pesticide products and devices for export.

Any label and labeling information requirements in §§ 168.69, 168.70, and 168.71 that are not met fully on the product label attached to the immediate product container may be met by collateral labeling that is either:

(a) Attached to the immediate product (container label); or

(b) Attached to or accompanies the shipping container of the export pesticide or export device at all times when it is shipped or held for shipment in the United States.

§ 168.68 [Removed and Reserved]

5. Remove and reserve § 168.68.

6. In § 168.69, revise paragraph (a) to read as follows:

§ 168.69 Registered export pesticide products.

(a) Each export pesticide product that is registered under FIFRA section 3 or FIFRA section 24(c) must bear labeling approved by EPA for its registration or collateral labeling in compliance with § 168.66.

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7. In § 168.70, revise the introductory text of paragraph (b) to read as follows:

§ 168.70 Unregistered export pesticide products.

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(b) Each unregistered export pesticide product must bear labeling that complies with all requirements of this section or collateral labeling in compliance with § 168.66:

* * * * *

8. In § 168.71, revise paragraph (a) to read as follows:

§ 168.71 Export pesticide devices.

(a) Each export pesticide device sold or distributed anywhere in the United States must bear labeling that complies with all requirements of this section or collateral labeling in compliance with § 168.66.

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